EXHIBIT 3

SUPREME COURT OF THE STATE OF NEW YORK
APPELLATE DIVISION: FOURTH DEPARTMENT

– X

MEDICAL PROFESSIONALS FOR INFORMED CONSENT, et al.

Appellees-Petitioners

Index No. CA 23-00161

-against-

MARY T. BASSETT, et al,

Appellants-Respondents

– X

STATE OF CONNECTICUT)
) ss.: TRUMBULL
COUNTY OF FAIRFIELD)

HARVEY A. RISCH, MD, PHD, being duly sworn, deposes and says:

1. I make this affidavit in support of Appellee-Petitioners' opposition to Appellants' motion for stay.

2. I am familiar with the facts set forth herein based on my review of the affidavits and evidence submitted with Appellants' motion for a stay, hundreds of scientific studies and research findings, on my own extensive research and on my personal knowledge and the expertise gained through my career as a university professor, research scientist and epidemiologist. Some of the credentials and experience that qualify me to give this opinion are listed below.

3. I am Professor Emeritus of Epidemiology at Yale School of Public Health, a practicing academic epidemiologist with more than 40 years of experience in epidemiologic methods, both in research and teaching. My research has included both infectious and noninfectious factors.

4. Over this career, I have taught introductory, intermediate, and advanced epidemiologic research methods to public health graduate students, postdoctoral fellows, hospital residents, and junior faculty members. I have also taught coursework on pharmacoepidemiology, which is the epidemiologic study of vaccines, medications, and medical devices, and their antecedent conditions and reasons for use.

5. I have published some 400 peer-reviewed original research papers in well-regarded scientific journals and have an h-index of 105, with more than 48,000 publication citations to-date.

6. I have served as grant reviewer or chair on two dozen grant review panels, most of which were at NIH, and served as peer reviewer for 60 scientific and medical journals.

7. I have been Associate Editor of the *Journal of the National Cancer Institute* since 2000, Member of the Board of Editors of the *American Journal of Epidemiology* from 2014-2020, and Editor of the *International Journal of Cancer* since 2008.

8. I am an elected member of the Connecticut Academy of Science and Engineering and, based on my strong epidemiologic methods experience and PhD work in infectious epidemic models, was selected to be a member of the Academy committee that was organized in 2020 to formulate plans for helping the reopening of the state of Connecticut after its lockdown ended.

9. I thus began researching COVID-19 epidemiology, prevention, treatment, and vaccination with my participation in the Reopening Committee. In the subsequent 2.5 years, I extensively studied medical and epidemiologic factors related to the COVID-19 virus, the vaccines, and the disease in the US and internationally.

10. I base my understandings of vaccine immunity and safety from studies and data of the three genetic vaccines that have received emergency use authorization (EUA) from the US Food and Drug Administration (FDA): the two mRNA-technology vaccines (Pfizer-BioNTech and Moderna) and the adenovirus vector-based vaccine (Johnson & Johnson).

11. In my professional opinion, Appellants' claim that a vaccine mandate will reduce the spread of COVID-19 in any meaningful way is not supported by the great weight of evidence and does not comport with the current recommendations of the Centers for Disease Control and Prevention ("CDC").

The Current Scientific Consensus, based on the Overwhelming Weight of Available Evidence, does not Support the Assertion that Vaccination can Meaningfully Stop the Spread of COVID-19

12. My understanding from the papers is that Appellants assert that maintaining a vaccine mandate pending the outcome of their appeal is necessary to stop the spread of COVID-19 in hospitals and healthcare facilities and thus prevent irreparable harm.

13. This claim is not supported by the scientific evidence, nor is it supported by the consensus of public health officials and scientists as represented by official CDC statements.

14. In fact, in 2022, CDC specifically updated its guidance to state, "CDC's COVID-19 prevention recommendations no longer differentiate on a person's vaccination status."[1]

15. As further discussed below, there is no reasonable scientific debate about the fact that the original primary COVID-19 vaccinations have essentially completely lost effectiveness for preventing infection transmission, nor about that currently available vaccines provide only transient

[1] Centers for Disease Control and Prevention. Summary of Guidance for Minimizing the Impact of COVID-19 on Individual Persons, Communities, and Health Care Systems — United States, August 2022. https://www.cdc.gov/mmwr/volumes/71/wr/mm7133e1.htm (August 19, 2022; last visited January 31, 2023)

benefit and wane in effectiveness, nor about that unvaccinated employees pose no different risk of spreading COVID-19 over those vaccinated with the two-dose primary series.

16. Given these well-established facts, there is no scientific basis to assert that a vaccine mandate will meaningfully stop the spread of COVID-19 in healthcare facilities, or that staying the lower court's decision to strike the mandate is necessary to prevent irreparable harm.

All Available Regular-Dose COVID-19 Vaccines Target the Original SARS-CoV-2 Virus, Rendering Them Largely Ineffective

17. All currently available COVID-19 vaccines were designed to target the spike (S) glyco-protein of the original SARS-CoV-2 strain (Wuhan HU-1) identified in Wuhan, China, in late 2019.

18. Since then, however, substantial mutations have occurred to that structure—at least fifteen mutations of the Spike S receptor-binding domain (RBD) have been identified in Omicron alone. (Cao et al., 2022a).[2]

19. This dramatic evolution of the variant has resulted in substantial antibody escape, estimated at above 85% of all neutralizing antibodies tested by the same group of researchers, in another study evading neutralizing antibodies with a twelve- to 44-fold higher efficiency than the Delta variant (Hoffmann et al., 2022).[3]

20. "Antibody escape" renders antibodies elicited against the earlier virus strains ineffective against the escaped substrains.

21. The Omicron subvariants present an even higher capacity for antibody escape while also becoming more transmissible due to additional mutations in the spike protein.

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[2] Cao Y, Wang J, Jian F, Xiao T, Song W, Yisimayi A, Huang W, Li Q, Wang P, An R, Wang J, Wang Y, Niu X, Yang S, Liang H, Sun H, Li T, Yu Y, Cui Q, Liu S, Yang X, Du S, Zhang Z, Hao X, Shao F, Jin R, Wang X, Xiao J, Wang Y, Xie XS. Omicron escapes the majority of existing SARS-CoV-2 neutralizing antibodies. Nature 2022a;602(7898):657-663. https://www.nature.com/articles/s41586-021-04385-3

[3] Hoffmann M, Krüger N, Schulz S, Cossmann A, Rocha C, Kempf A, Nehlmeier I, Graichen L, Moldenhauer AS, Winkler MS, Lier M, Dopfer-Jablonka A, Jäck HM, Behrens GMN, Pöhlmann S. The Omicron variant is highly resistant against antibody-mediated neutralization: Implications for control of the COVID-19 pandemic. Cell 2022;185(3):447-456.e11. https://www.cell.com/cell/fulltext/S0092-8674(21)01495-1

22. Specifically, more recently circulating variants like BA.4 and BA.5 are some four-fold more resistant to "sera from vaccinated and boosted individuals than BA.2," which itself was already more resistant than the baseline Omicron variant (Wang et al., 2022).[4] Omicron variants in turn have been far more resistant than Delta, which was more resistant than the original virus strains to original vaccine-related immunity.

23. In other words, vaccination with the primary series, which is what this mandate requires, has little to no effect on a person's ability to become infected and/or pass on currently circulating strains of SARS-CoV-2, and may in fact even be counterproductive.

24. The data further show that, even for currently available vaccine boosters updated to target Omicron subvariant BA.1, the recent mutations in BA.5 render such an update largely ineffective (Cao et al., 2022b).[5]

25. Similarly, bivalent booster vaccines targeting BA.4 and BA.5 are highly ineffective against current substrains BQ.1.1 and XBB.1 (Miller et al., 2023).[6]

26. These substrains together comprise the overwhelming majority of virus variants presently in circulation in the US (see CDC chart, next page, dated January 28, 2023).[7]

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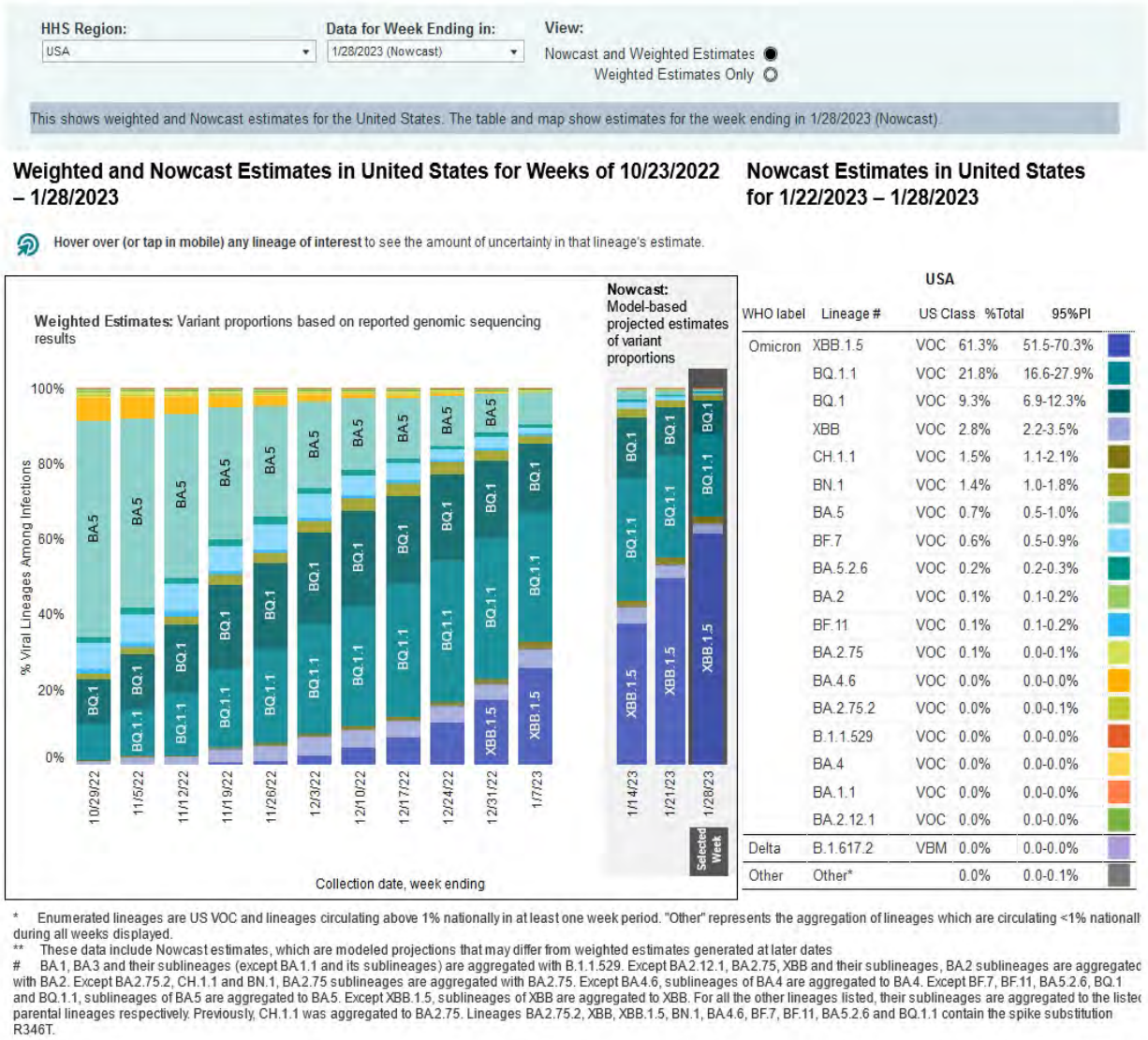
[4] Wang Q, Guo Y, Iketani S, Nair MS, Li Z, Mohri H, Wang M, Yu J, Bowen AD, Chang JY, Shah JG, Nguyen N, Chen Z, Meyers K, Yin MT, Sobieszczyk ME, Sheng Z, Huang Y, Liu L, Ho DD. Antibody evasion by SARS-CoV-2 Omicron subvariants BA.2.12.1, BA.4 and BA.5. Nature 2022 Aug;608(7923):603-608. https://www.nature.com/articles/s41586-022-05053-w

[5] Cao Y, Yisimayi A, Jian F, Song W, Xiao T, Wang L, Du S, Wang J, Li Q, Chen X, Yu Y, Wang P, Zhang Z, Liu P, An R, Hao X, Wang Y, Wang J, Feng R, Sun H, Zhao L, Zhang W, Zhao D, Zheng J, Yu L, Li C, Zhang N, Wang R, Niu X, Yang S, Song X, Chai Y, Hu Y, Shi Y, Zheng L, Li Z, Gu Q, Shao F, Huang W, Jin R, Shen Z, Wang Y, Wang X, Xiao J, Xie XS. BA.2.12.1, BA.4 and BA.5 escape antibodies elicited by Omicron infection. Nature 2022b;608(7923):593-602. https://www.nature.com/articles/s41586-022-04980-y

[6] Miller J, Hachmann NP, Collier AY, Lasrado N, Mazurek CR, Patio RC, Powers O, Surve N, Theiler J, Korber B, Barouch DH. Substantial neutralization escape by SARS-CoV-2 Omicron variants BQ.1.1 and XBB.1. N Engl J Med. 2023 Jan 18. https://www.nejm.org/doi/full/10.1056/NEJMc2214314

[7] Centers for Disease Control and Prevention. Variant Proportions. https://covid.cdc.gov/covid-data-tracker/#variant-proportions (2023; last visited January 28, 2023)



Vaccine Protection Wanes More Rapidly than Natural Infection

27. By four to six months after the full course of either the Pfizer or Moderna vaccines, protection against infection by the BA.1 or BA.2 subvariants is estimated to be somewhere between zero to thirty percent—in other words, almost entirely attenuated only six months after the last injection (UK Health Security Agency, 2022).[8]

[8] UK Health Security Agency. COVID-19 Vaccine Surveillance Report, Week 27, Publishing reference: GOV-12727, July 7, 2022. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1088974/Vaccine-surveillance-report-week-27.pdf (last visited January 30, 2023).

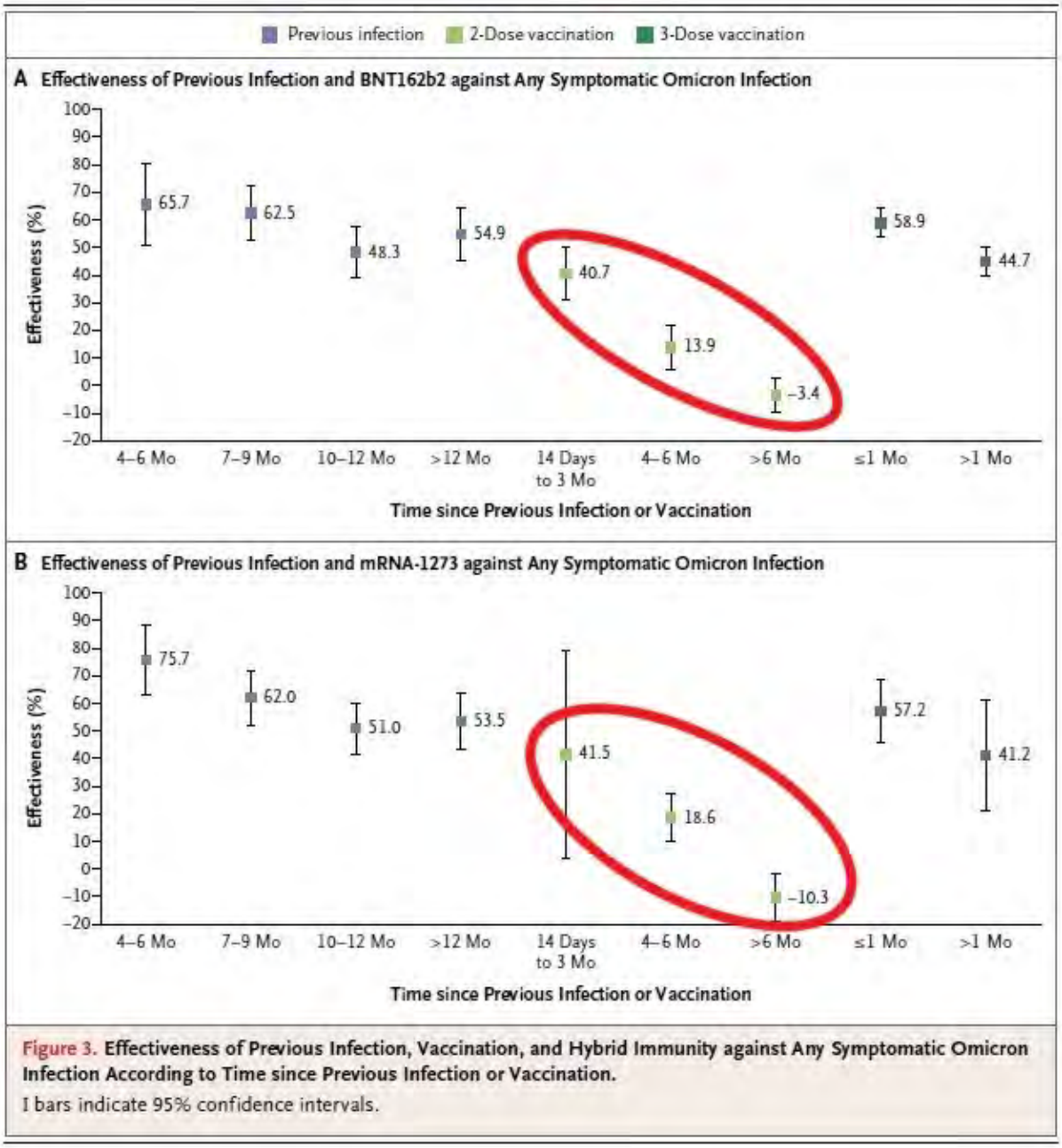


Figure 3. Effectiveness of Previous Infection, Vaccination, and Hybrid Immunity against Any Symptomatic Omicron Infection According to Time since Previous Infection or Vaccination.

I bars indicate 95% confidence intervals.

28. Dozens of studies show that circulating antibodies, T-cells and B-cells reflective of SARS-CoV-2 infection last at least as long, and in most cases longer than, protection from vaccination (Alexander, 2022).[9]

[9] Alexander PE. 160 Plus Research Studies Affirm Naturally Acquired Immunity to Covid-19: Documented, Linked, and Quoted. Brownstone Institute, 2022. https://brownstone.org/articles/research-studies-affirm-naturally-acquired-immunity/ (last accessed January 30, 2023)

29. Moreover, multiple other studies show conclusively that any protection the vaccine two-dose regimen can provide against Omicron infection wanes by six months (Kirsebom et al., 2022[10]; Tseng et al., 2022[11]; Nielsen et al., 2022[12]; Altarawneh et al., 2022[13]). The relevant Figure 3 from the Altarawneh study is shown at the top of the previous page (2-dose vaccination circled in red).

30. The Qatar study (Altarawneh et al., 2022) also shows in that figure that in contrast to vaccine effectiveness, previous infection effectiveness against reinfection remains stable for at least one year.

31. One empirical study of 11,000 UK healthcare workers demonstrates strong resistance to reinfection for at least 6 months.[14]

[10] Kirsebom FCM, Andrews N, Stowe J, Toffa S, Sachdeva R, Gallagher E, Groves N, O'Connell A-M, Chand M, Ramsay M, Lopez Bernal J. COVID-19 vaccine effectiveness against the omicron (BA.2) variant in England. Lancet Infect Dis 2022; published online May 24. https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00309-7/fulltext

[11] Tseng HF, Ackerson BK, Bruxvoort KJ, Sy LS, Tubert JE, Lee GS, Ku JH, Florea A, Luo Y, Qiu S, Choi SK, Takhar HS, Aragones M, Paila YD, Chavers S, Talarico CA, Qian L. Effectiveness of mRNA-1273 against infection and COVID-19 hospitalization with SARS-CoV-2 Omicron subvariants: BA.1, BA.2, BA.2.12.1, BA.4, and BA.5. medRxiv preprint, December 2, 2022. https://www.medrxiv.org/content/10.1101/2022.09.30.22280573v2

[12] Nielsen KF, Moustsen-Helms IR, Schelde AB, Gram MA, Emborg HD, Nielsen J, Hansen CH, Andersen MA, Meaidi M, Wohlfahrt J, Valentiner-Branth P. Vaccine effectiveness against SARS-CoV-2 reinfection during periods of Alpha, Delta, or Omicron dominance: A Danish nationwide study. PLoS Med 2022;19(11):e1004037. https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1004037

[13] Altarawneh HN, Chemaitelly H, Ayoub HH, Tang P, Hasan MR, Yassine HM, Al-Khatib HA, Smatti MK, Coyle P, Al-Kanaani Z, Al-Kuwari E, Jeremijenko A, Kaleeckal AH, Latif AN, Shaik RM, Abdul-Rahim HF, Nasrallah GK, Al-Kuwari MG, Butt AA, Al-Romaihi HE, Al-Thani MH, Al-Khal A, Bertollini R, Abu-Raddad LJ. Effects of Previous Infection and Vaccination on Symptomatic Omicron Infections. N Engl J Med 2022;387(1):21-34. https://www.nejm.org/doi/10.1056/NEJMoa2203965

[14] Hanrath AT, Payne BAI, Duncan CJA. Prior SARS-CoV-2 infection is associated with protection against symptomatic reinfection. J Infect 2021;82(4):e29-e30. https://www.journalofinfection.com/article/S0163-4453(20)30781-7/fulltext

32. Four empirical studies demonstrate strong resistance to reinfection for at least 7 months, in Qatar,[15] Denmark,[16] UK[17] and Austria.[18]

33. One empirical study in the London, UK, metropolitan area demonstrates strong resistance to reinfection for at least 8 months.[19]

34. Three empirical studies demonstrate strong resistance to reinfection for at least 9 months, in England,[20] Israel[21] and the US,[22] and another in the US for 10 months.[23]

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[15] Abu-Raddad LJ, Chemaitelly H, Coyle P, Malek JA, Ahmed AA, Mohamoud YA, Younuskunju S, Ayoub HH, Al Kanaani Z, Al Kuwari E, Butt AA, Jeremijenko A, Kaleeckal AH, Latif AN, Shaik RM, Abdul Rahim HF, Nasrallah GK, Yassine HM, Al Kuwari MG, Al Romaihi HE, Al-Thani MH, Al Khal A, Bertollini R. SARS-CoV-2 antibody-positivity protects against reinfection for at least seven months with 95% efficacy. EClinicalMedicine 2021;35:100861. https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(21)00141-3/fulltext

[16] Hansen CH, Michlmayr D, Gubbels SM, Mølbak K, Ethelberg S. Assessment of protection against reinfection with SARS-CoV-2 among 4 million PCR-tested individuals in Denmark in 2020: a population-level observational study. Lancet 2021;397(10280):1204-1212. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00575-4/fulltext

[17] Lumley SF, O'Donnell D, Stoesser NE, Matthews PC, Howarth A, Hatch SB, Marsden BD, Cox S, James T, Warren F, Peck LJ, Ritter TG, de Toledo Z, Warren L, Axten D, Cornall RJ, Jones EY, Stuart DI, Screaton G, Ebner D, Hoosdally S, Chand M, Crook DW, O'Donnell AM, Conlon CP, Pouwels KB, Walker AS, Peto TEA, Hopkins S, Walker TM, Jeffery K, Eyre DW; Oxford University Hospitals Staff Testing Group. Antibody Status and Incidence of SARS-CoV-2 Infection in Health Care Workers. N Engl J Med 2021;384(6):533-540. https://www.nejm.org/doi/10.1056/NEJMoa2034545

[18] Pilz S, Chakeri A, Ioannidis JP, Richter L, Theiler-Schwetz V, Trummer C, Krause R, Allerberger F. SARS-CoV-2 re-infection risk in Austria. Eur J Clin Invest 2021;51(4):e13520. https://onlinelibrary.wiley.com/doi/10.1111/eci.13520

[19] Breathnach AS, Riley PA, Cotter MP, Houston AC, Habibi MS, Planche TD. Prior COVID-19 significantly reduces the risk of subsequent infection, but reinfections are seen after eight months. J Infect 2021 Apr;82(4):e11-e12. https://www.journalofinfection.com/article/S0163-4453(21)00010-4/fulltext

[20] Hall VJ, Foulkes S, Charlett A, Atti A, Monk EJM, Simmons R, Wellington E, Cole MJ, Saei A, Oguti B, Munro K, Wallace S, Kirwan PD, Shrotri M, Vusirikala A, Rokadiya S, Kall M, Zambon M, Ramsay M, Brooks T, Brown CS, Chand MA, Hopkins S; SIREN Study Group. SARS-CoV-2 infection rates of antibody-positive compared with antibody-negative health-care workers in England: a large, multicentre, prospective cohort study (SIREN). Lancet 2021;397(10283):1459-1469. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00675-9/fulltext

[21] Gazit S, Shlezinger R, Perez G, Lotan R, Peretz A, Ben-Tov A, Herzel E, Alapi H, Cohen D, Muhsen K, Chodick G, Patalon T. The Incidence of SARS-CoV-2 Reinfection in Persons With Naturally Acquired Immunity With and Without Subsequent Receipt of a Single Dose of BNT162b2 Vaccine : A Retrospective Cohort Study. Ann Intern Med 2022;175(5):674-681. https://www.acpjournals.org/doi/full/10.7326/M21-4130

[22] León TM, Dorabawila V, Nelson L, Lutterloh E, Bauer UE, Backenson B, Bassett MT, Henry H, Bregman B, Midgley CM, Myers JF, Plumb ID, Reese HE, Zhao R, Briggs-Hagen M, Hoefer D, Watt JP, Silk BJ, Jain S, Rosenberg ES. COVID-19 Cases and Hospitalizations by COVID-19 Vaccination Status and Previous COVID-19 Diagnosis - California and New York, May-November 2021. MMWR Morb Mortal Wkly Rep 2022;71(4):125-131. https://www.cdc.gov/mmwr/volumes/71/wr/mm7104e1.htm

[23] Spicer KB, Glick C, Cavanaugh AM, Thoroughman D. Protective Immunity after Natural Infection with Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) - Kentucky, USA, 2020. Int J Infect Dis 2022;114:21-28. https://www.ijidonline.com/article/S1201-9712(21)00800-6/fulltext

35. Finally, one empirical study in Italy demonstrates strong resistance to reinfection for at least 11 months,[24] and one at the Cleveland Clinic in the US, for at least 13 months.[25]

36. These twelve empirical studies demonstrate that natural infection with SARS-CoV-2 generates effective immunity in dramatically reducing risk of reinfection for at least 6-13 months. Such reduced risks are comparable to or more durable than the temporary reduced infection risks lasting roughly no more than 6 months provided by vaccination, as shown above.

37. Appellants' own data set also shows that natural immunity is superior to vaccine immunity. CDC analysis of the NYSDOH COVID-19 cumulative laboratory-confirmed incidence data for the period May through November 2021 showed that 1.82% of vaccinated people without previous COVID-19 diagnosis got COVID-19, vs 0.62% of unvaccinated people who had previously had COVID-19, an almost 3-fold higher rate for vaccinated individuals[26] . This study was co-authored by Respondent-Appellant Bassett and Appellants' Affiant Dr. Emily Lutterloh in January 2022.

38. The same CDC report found almost identical rates in California for the same period: 1.55% of vaccinated people without previous COVID-19 diagnosis got COVID-19, vs 0.50% of unvaccinated people who had previously had COVID-19, again a 3-fold rate for vaccinated vs unvaccinated persons.

39. Similarly, the primary study that Dr. Lutterloh relies on in the affidavit submitted with these motion papers also found that vaccine effectiveness wanes over months, whereas immunity from natural infection does not. "We … found that time since last dose of a COVID-19 vaccine (as a continuous variable) was associated with increased infectiousness of SARS Co-V2-infections. … We

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[24] Vitale J, Mumoli N, Clerici P, De Paschale M, Evangelista I, Cei M, Mazzone A. Assessment of SARS-CoV-2 Reinfection 1 Year After Primary Infection in a Population in Lombardy, Italy. JAMA Intern Med 2021;181(10):1407-1408. https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2780557

[25] Kim P, Gordon SM, Sheehan MM, Rothberg MB. Duration of Severe Acute Respiratory Syndrome Coronavirus 2 Natural Immunity and Protection Against the Delta Variant: A Retrospective Cohort Study. Clin Infect Dis 2022;75(1):e185-e190. https://academic.oup.com/cid/article/75/1/e185/6448857

[26] *See* fn 22, *supra.*

did not observe a statistically significant relationship between time since last SARS-Co-V2 infection and risk of transmission." (NYSCEF Doc. 3 at p. 225, *Lutterloh Ex. B*) (Tan et al., 2023).[27] This means that increasingly over months after the last vaccine dose, risk of infection significantly increased, whereas after prior infection, a significant increasing risk of reinfection was not seen.

40. I am informed that all named Petitioners and most healthcare workers seeking reinstatement as a result of the lower court's order have natural immunity. The science does not support an inference that their return to work will pose a direct threat to public health.

41. Dr. Lutterloh states that natural immunity should not apply to COVID-19 mandates (NYSCEF Doc. 3, Ex. L - Lutterloh Aff. ¶ 12 fn 3). In particular, she notes, "Serology is appropriate for diseases people typically only contract once in their lifetime, well characterized serology is reliably commercially available, and positive serology indicates essentially complete immunity. COVID-19 does not fit this profile."

42. Respectfully, these three criteria do not represent the purpose of documenting serological evidence of having had COVID-19. The evidence cited herein at ¶¶ 28-35 shows that prior SARS-CoV-2 infection reduces the risk of reinfection in degree comparable to and for durations longer than 2-dose vaccine-based immunity. A serological test positive for indicators of natural immunity to SARS-CoV-2 is extremely specific for having previously had COVID-19. There is no requirement to demonstrate complete immunity by serologic evidence; there is no requirement that the previous COVID-19 not have occurred more than once, nor that infection could not theoretically recur, as breakthrough infections certainly can after vaccination (see ¶ 43 *infra*); and commercial testing for natural COVID-19 serology is available.[28] A positive commercial serologic test demonstrates the

[27] Tan ST, Kwan AT, Rodríguez-Barraquer I, Singer BJ, Park HJ, Lewnard JA, Sears D, Lo NC. Infectiousness of SARS-CoV-2 breakthrough infections and reinfections during the Omicron wave. Nat Med 2023 Jan 2. https://www.nature.com/articles/s41591-022-02138-x

[28] https://www.questdiagnostics.com/patients/get-tested/conditions/infectious-disease/covid-19/antibody

fact of past COVID-19, and that fact is sufficient to assert durable immunity to reinfection by the virus, as good as or better than receipt of the primary series of vaccination required by the NYSDOH regulation at issue.

43. As discussed herein, 2-dose COVID-19 vaccine immunity does not provide complete immunity, and it does not protect the vaccinated individual from getting or transmitting COVID-19. The criteria stated by Dr. Lutterloh at ¶ 41 are not imposed on vaccine-based immunity and are therefore not comparable between vaccine-based and natural immunity. These criteria represent an ad hoc and arbitrarily incorrect characterization of the fact of a positive result in commercial serologic testing for past COVID-19.

Currently Available Vaccines May Actually Increase
The Risk of Infection or Transmission of SARS-CoV-2

44. Data from a number of more recent high-powered studies show that currently available vaccines may eventually actually increase the risk of infection and transmission of COVID-19 rather than decrease it.

45. A study performed during Qatar's Omicron wave in December 2021 to mid-January 2022 involving more than 1.6 million persons bears out this fact by demonstrating that any previous protection afforded by full primary doses of the currently available vaccines no longer exists (Altarawneh et al., 2022).[29]

46. The Qatar national study showed that full vaccination with either BNT162b2 (Pfizer) or mRNA-1273 (Moderna) had "negligible" effectiveness to prevent infection, and that the vaccines were conferring null or negative efficacy—in other words, by six months after vaccination, **those vaccinated but not boosted were more likely to develop symptomatic infections than unvaccinated individuals.** (Altarawneh et al., 2022)[30] (see earlier figure).

[29] *See* fn 13, *supra.*
[30] *Id.*

47. The same eventual negative efficacy is seen after five months post-vaccination in the large Southern California Kaiser Permanente study by Tseng et al. (Tseng et al., 2022).[31]

48. The same eventual negative efficacy is seen after eight months post-vaccination in the large Swedish study by Nordström et al. (Nordström et al., 2022).[32]

49. Public Health UK data from March 2022 similarly show that boosted adults in all age groups had approximately three times the infection risk of unvaccinated adults (UK Health Security Agency, 2022).[33]

50. Even if there were some average behavioral differences between the vaccinated and unvaccinated individuals in the UK data, these would be very unlikely to have accounted for the large observed increased infection risks in the vaccinated, let alone suggest that the vaccinated should have had lower risk. Whatever general health differences might have tended to have been present in vaccinated vs unvaccinated individuals at the beginning of the UK vaccine rollouts were largely dissipated by March 2022 to which these data pertain.

51. Follow-up data of some 51,000 Cleveland Clinic health-care employees shows that the cumulative risk of getting COVID-19 is positively directly related to the number of previous vaccine doses (0, 1, 2, 3, >3) received (Shrestha et al., 2022)[34] (figure at top of next page). These risk differences between doses were statistically significant, and again demonstrate that vaccination is not associated with decreased risk of SARS-CoV-2 infection but quite possibly with increased risk.

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[31] *See* fn 8, *supra.*

[32] Nordström P, Ballin M, Nordström A. Risk of infection, hospitalisation, and death up to 9 months after a second dose of COVID-19 vaccine: a retrospective, total population cohort study in Sweden. Lancet 2022 (399), February 26. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)00089-7/fulltext

[33] UK Health Security Agency. COVID-19 vaccine surveillance report Week 13, Publishing reference: GOV-11859, March 31, 2022. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1066759/Vaccine-surveillance-report-week-13.pdf (last visited January 22, 2023).

[34] Shrestha NK, Burke PC, Nowacki AS, Simon JF, Hagen A, Gordon SM. Effectiveness of the Coronavirus Disease 2019 (COVID-19) Bivalent Vaccine. medRxiv preprint, December 19, 2022. https://www.medrxiv.org/content/10.1101/2022.12.17.22283625v1

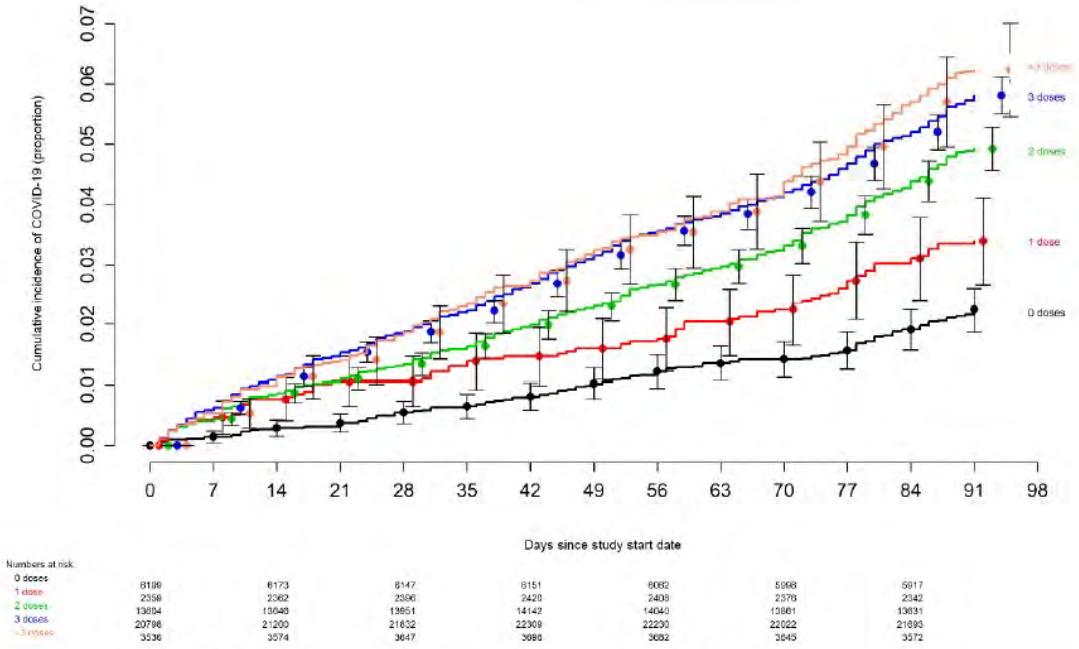

Figure 2. Simon-Makuch plot comparing the cumulative incidence of COVID-19 for subjects stratified by the number of COVID-19 vaccine doses previously received. Day zero was 12 September 2022, the day the bivalent vaccine began to be offered to employees. Point estimates and 95% confidence intervals are jittered along the x-axis to improve visibility.

52. All of these data comprise definitive, large-scale evidence that the vaccines do not provide public-health benefit in reducing SARS-CoV-2 transmission, and within a few months after the last dose, may even potentially increase transmission risks.

53. Thus, as discussed *infra* starting at ¶ 54, government and public health officials have recognized that the currently available vaccines do not protect against infection transmission.[35]

[35] The raw NYSDOH COVID-19 breakthrough infection tracker data cited by Dr. Lutterloh (NYSCEF Doc. 3, Ex. L - Lutterloh Aff. ¶ 8 fn 1) on infection risk in vaccinated vs unvaccinated individuals do not bear upon the risk of COVID-19 *re*infection. According to CDC NY state data in the León et al. publication (*See* fn 22, *supra.*), unvaccinated New Yorkers who had had previous COVID-19 infection comprised 20.9% of all unvaccinated individuals by the time of the study analysis. The breakthrough infection tracker data thus include a very large majority who have not previously had COVID-19 and are at much higher risk of infection than those previously infected.

54. The CDC, for example, acknowledged that whatever protection against transmission or infection that the currently available vaccines might have afforded against earlier variants, transmission can occur with Omicron regardless of vaccination status. They state, "Omicron spreads more easily than earlier variants, including the Delta variant. **Anyone with Omicron infection, regardless of vaccination status or whether or not they have symptoms, can spread the virus to others.**" (Centers for Disease Control and Prevention, 2022).[36]

55. There are no statements on this CDC web page making any assertions that the vaccines have a benefit for preventing infection transmission.

56. On August 11, 2022, CDC conceded that the COVID-19 vaccines do not provide sustained public health infection or transmission benefit: "Receipt of a primary series alone, in the absence of being up to date with vaccination* through receipt of all recommended booster doses, provides minimal protection against infection and transmission (3,6). Being up to date with vaccination provides a transient period of increased protection against infection and transmission after the most recent dose, although protection can wane over time." (Massetti et al., 2022).[37]

57. The term "transient" means a short period of time, thus these vaccines do not serve an appreciable public health function in sustained reduction of infection or transmission risks.

58. And, while Attorney Brockner asserts that the CDC recommends that healthcare workers follow COVID-19 vaccination recommendations and requirements, he fails to mention that the CDC has updated guidance for healthcare workers to specifically caution that "[c]onventional strategies were updated to advise that, in most circumstances, asymptomatic healthcare personnel with

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[36] Centers for Disease Control and Prevention. Omicron Variant: What You Need to Know. https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html (August 11, 2021; last visited January 22, 2023)

[37] Massetti GM, Jackson BR, Brooks JT, Perrine CG, Reott E, Hall AJ, Lubar D, Williams IT, Ritchey MD, Patel P, Liburd LC, Mahon BE. Summary of Guidance for Minimizing the Impact of COVID-19 on Individual Persons, Communities, and Health Care Systems - United States, August 2022. MMWR Morb Mortal Wkly Rep 2022;71(33):1057-1064. https://www.cdc.gov/mmwr/volumes/71/wr/mm7133e1.htm

higher-risk exposures do not require work restrictions, regardless of their vaccination status."[38] (NYSCEF Doc. 3, Ex. F at 103) as well as that "vaccination status is no longer used to inform source control, screening testing, or post-exposure recommendations."[39]

59. Nor do Appellants mention CDC's updated generalized guidance in 2022, stating that "CDC's COVID-19 prevention recommendations no longer differentiate on a person's vaccination status.[40]

60. **Given that the vaccines do not prevent COVID-19 infection or transmission and are officially acknowledged not to do so, clearly there can be no benefit for mandating their usage.**

61. The regulation at issue mandated that the primary series be completed in 2021 and does not at this time appear to include any booster requirement.

62. Given the fact that vaccine efficacy wanes substantially in a matter of a few months, there is no rational basis to exclude unvaccinated healthcare workers but allow healthcare workers to come to work who had their last dose some two years ago.

63. Nor would the addition of a booster requirement justify the mandate from a public health perspective.

64. The booster vaccines recently released for the fall 2022/winter 2023 season are already appearing to show failure to provide appreciable public health value. This is because, just like the original vaccine doses, they have only transient benefit toward their targeted substrains BA.4 and BA.5, as well as that those substrains have already lost predominance in the US. The CDC chart provided

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[38] Centers for Disease Control and Prevention. Strategies to Mitigate Healthcare Personnel Staffing Shortages. https://www.cdc.gov/coronavirus/2019-ncov/hcp/mitigating-staff-shortages.html (September 23, 2022; last visited January 30, 2023)

[39] Centers for Disease Control and Prevention. Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic. https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html (September 23, 2022; last visited January 30, 2023)

[40] *See* fn 1, *supra*.

earlier shows that these Omicron variants are now of negligible circulation. The current substrains, BQ.1.1 and XBB.1, largely escape neutralization by antibodies resulting from the bivalent vaccine booster (Kurhade et al., 2022[41]; Davis-Gardner et al., 2023[42]; Miller et al., 2023[43]; Uraki et al., 2023[44]).

65. Because the COVID-19 vaccines, both the original formulations and the bivalent boosters, fail to provide any sustained suppression of population infection spread, they are inadequate as agents for pandemic control. This officially acknowledged lack of efficacy makes mandates for them, both for the original two-dose vaccines as well as for monovalent or bivalent boosters, unwarranted.

Conclusion

66. By a large body of evidence, as well as by official statements of the CDC, there is no difference in risk of SARS-CoV-2 transmission by vaccinated vs unvaccinated individuals.

67. It is not a scientifically supportable position to state that maintenance of a vaccine mandate requiring the primary series of vaccines (effective 2021) is necessary to avoid irreparable harm.

68. On the contrary, particularly in an unprecedented staffing crisis, it would instead cause irreparable harm to patients and caregivers to continue to ban, based on their failure to receive the first two doses of the COVID-19 vaccine, ready, willing and able experienced doctors, nurses and other healthcare personnel from returning to work.

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[41] Kurhade C, Zou J, Xia H, Liu M, Chang HC, Ren P, Xie X, Shi PY. Low neutralization of SARS-CoV-2 Omicron BA.2.75.2, BQ.1.1 and XBB.1 by parental mRNA vaccine or a BA.5 bivalent booster. Nat Med 2022 Dec 6. https://www.nature.com/articles/s41591-022-02162-x

[42] Davis-Gardner ME, Lai L, Wali B, Samaha H, Solis D, Lee M, Porter-Morrison A, Hentenaar IT, Yamamoto F, Godbole S, Liu Y, Douek DC, Lee FE, Rouphael N, Moreno A, Pinsky BA, Suthar MS. Neutralization against BA.2.75.2, BQ.1.1, and XBB from mRNA Bivalent Booster. N Engl J Med 2023;388(2):183-185. https://www.nejm.org/doi/full/10.1056/NEJMc2214293

[43] *See* fn 6, *supra*

[44] Uraki R, Ito M, Furusawa Y, Yamayoshi S, Iwatsuki-Horimoto K, Adachi E, Saito M, Koga M, Tsutsumi T, Yamamoto S, Otani A, Kiso M, Sakai-Tagawa Y, Ueki H, Yotsuyanagi H, Imai M, Kawaoka Y. Humoral immune evasion of the omicron subvariants BQ.1.1 and XBB. Lancet Infect Dis 2023;23(1):30-32. https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00816-7/fulltext

Dated: February 1, 2023

Harvey A. Risch

Affirmed before me this 1st day of February 2023.

Notary Public

SOPHIA NADHAZI
Notary Public, State of Connecticut
My Commission Expires Dec. 31, 2023